UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK

CV-14 3549

UNITED STATES OF AMERICA,

Plaintiff,

v.

MIRA HEALTH PRODUCTS LTD., a corporation, et al.,

Defendants.

CIVIL ACTION NO._____

CONSENT DECREE FOR PERMANENT INJUNCTION

BIANCO, J.
BROWN, M. J.

Plaintiff, the United States of America, by and through its undersigned counsel, having filed a Complaint For Permanent Injunction (the "Complaint") against Mira Health Products Ltd., a corporation, and Michael S. Ragno and Michael S. Ragno, Jr., individuals (collectively, "Defendants"), and Defendants having appeared and consented to entry of this Decree without contest, without admitting or denying the allegations of the Complaint, and before any testimony has been taken, and the United States of America, having consented to this Decree;

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED as follows:

1. This Court has jurisdiction over the subject matter and all parties to this action.

2. The Complaint states a cause of action against Defendants under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 *et seq.* (the "Act").

3. The Complaint alleges that Defendants violate 21 U.S.C. § 331(a), by introducing or delivering for introduction, and causing to be introduced or delivered for introduction, into interstate commerce articles of drugs that are misbranded within the meaning of 21 U.S.C. § 352(f)(1) in that their labeling fails to bear adequate directions for use.

4. The Complaint alleges that Defendants violate 21 U.S.C. § 331(k), by causing drugs that Defendants hold for sale after shipment in interstate commerce to become misbranded

within the meaning of 21 U.S.C. § 352(f)(1) in that their labeling fails to bear adequate directions for use.

5. The Complaint alleges that Defendants violate 21 U.S.C. § 331(a) by introducing or delivering, or causing to be introduced or delivered, into interstate commerce dietary supplements, as defined by 21 U.S.C. § 321(ff), that are adulterated within the meaning of 21 U.S.C. § 342(g)(1) in that they have been prepared, packed, and held under conditions that do not meet current good manufacturing practice regulations for dietary supplements ("Dietary Supplement CGMP"). 21 C.F.R. Part 111.

6. The Complaint alleges that Defendants violate 21 U.S.C. § 331(k) by causing dietary supplements that Defendants hold for sale after shipment in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 342(g)(1).

7. Upon entry of this Decree, Defendants represent to the Court that they are not directly or indirectly engaged in manufacturing, processing, packing, labeling, holding, or distributing any dietary supplement, any product labeled as such, or any drug. If Defendants later intend to resume operations at 65 E. Carmans Road, Farmingdale, New York 11735, or any other location, Defendants must first notify FDA in writing at least sixty (60) business days in advance of resuming operations and must comply with paragraphs 8(A)-(G) and 8(I) of this Decree. This notice shall identify the type(s) of dietary supplements Defendants intend to manufacture, process, pack, label, hold and/or distribute, and the facility in which Defendants intend to resume operations. Defendants shall not resume operations until FDA has first inspected Defendants' facility and operations pursuant to paragraph 8(H), Defendants have paid the costs of such inspection(s) pursuant to paragraph 8(I), and Defendants have received written

notice from FDA, as required by paragraph 8(J), and then Defendants shall resume such dietary supplement operations only to the extent authorized in FDA's written notice.

8. Upon entry of this Decree, Defendants and each and all of their directors, officers, agents, representatives, employees, attorneys, successors and assigns, and any and all persons or entities in active concert or participation with any of them who have received actual notice of this Decree by personal service or otherwise are permanently restrained and enjoined under 21 U.S.C. § 332(a), and the inherent equitable authority of this Court, from directly or indirectly manufacturing, processing, packing, labeling, holding, or distributing any dietary supplement, any product labeled as such, or any drug at or from 65 E. Carmans Road, Farmingdale, New York 11735 (the "facility"), or at or form any other location(s) at which Defendants, now or in the future, directly or indirectly manufacture, prepare, process, package, pack, label, hold, and/or distribute dietary supplements, any product labeled as such, or any drug unless and until:

A. Defendants have removed all claims from their product labels, labeling, websites owned or controlled by Defendants, and in any other media that cause that product to be a drug within the meaning of the Act;

B. Defendants retain, at Defendants' expense, an independent person or persons (the "Labeling Expert"), who is without personal, financial (other than the consulting agreement between the parties), or familial ties to Defendants and their families or affiliates, who by reason of background, experience, education, and training is qualified to assess Defendants' compliance with the Act, to review the claims Defendants make for each of their products on all labels, labeling, and any internet websites owned or controlled by Defendants. Defendants shall notify FDA in writing of the identity and qualifications of the Labeling Expert as soon as they retain such expert. At the conclusion of the Labeling Expert's review, the Labeling Expert shall

prepare a written report analyzing whether Defendants are operating in compliance with the Act and in particular, certify whether Defendants have removed all claims from each of their product labels, labeling, websites owned or controlled by Defendants, and in any other media that cause any of Defendants' products to be drugs within the meaning of the Act, 21 U.S.C. § 321(g). The report shall include the specific results of the Labeling Expert's review, including references to product names and regulations addressed in the process of conducting the review. The report shall also include copies of all materials reviewed by the Labeling Expert. The Labeling Expert shall submit this report concurrently to Defendants and FDA no later than ten (10) business days after completing this review;

C. Defendants retain, at Defendants' expense, an independent person or persons (the "Dietary Supplement CGMP Expert"), who is without any personal or financial ties (other than the retention agreement) to Defendants and/or their families, and who, by reason of background, training, education, or experience, is qualified to inspect Defendants' facility to determine whether the facility, methods, processes, and controls are operated and administered in conformity with Dietary Supplement CGMP, 21 C.F.R. Part 111. Defendants shall notify FDA in writing of the identity and qualifications of the Dietary Supplement CGMP Expert as soon as they retain such expert;

D. The Dietary Supplement CGMP Expert performs a comprehensive inspection of Defendants' facility and the methods and controls used to manufacture, prepare, pack, label, and hold dietary supplements, and certifies in writing to FDA (1) that he or she has inspected Defendants' facility, methods, processes, and controls; and (2) whether Defendants' operations are, in the Dietary Supplement CGMP Expert's opinion, compliant with this Decree, the Act, and its implementing regulations. The Dietary Supplement CGMP Expert's report of

the inspection, which shall be submitted to FDA, shall include, but not be limited to, a determination of whether Defendants have methods, processes, and controls to ensure that they:

(1) Maintain, clean, and sanitize, as necessary, all equipment, utensils, and other contact surfaces used to manufacture, package, label, or hold components or dietary supplements, as required by 21 C.F.R. § 111.27(d);

(2) Conduct at least one appropriate test or examination to verify the identity of every component that is a dietary ingredient before using such components, as required by 21 C.F.R. § 111.75(a)(1)(i);

(3) Confirm the identity of every component that is not a dietary ingredient and determine whether applicable component specifications are met before using such components, as required by 21 C.F.R. § 111.75(a)(2);

(4) Verify that finished batches of dietary supplements meet product specifications for identity, purity, strength, and composition, as required by 21 C.F.R. § 111.75(c);

(5) Include in the batch production records complete information relating to the production and control of each batch, as required by 21 C.F.R. § 111.255(b). Pursuant to 21 C.F.R. § 111.260, such information includes:

(i) The unique identifier assigned to each component, packaging, and label used (21 C.F.R. § 111.260(d));

(ii) The identity and weight or measure of each component used (21 C.F.R. § 111.260(e));

(iii) A statement of the actual yield and a statement of the percentage of theoretical yield at appropriate phases of processing (21 C.F.R. § 111.260(f));

(iv) Documentation, at the time of performance, of packaging and labeling operations, including the unique identifier assigned to packaging and labels used (21 C.F.R. § 111.260(k)(1));

(v) Documentation, at the time of performance, of packaging and labeling operations, including an actual representative label, or a cross-reference to the physical location of the actual or representative label specified in the master manufacturing record (21 C.F.R. § 111.260(k)(2));

(vi) Documentation, at the time of performance, that quality control personnel approved and released, or rejected, the batch for distribution (21 C.F.R. § 111.260(l)(3));

(6) Maintain batch production records so that such records accurately follow the appropriate master manufacturing record and demonstrate that each step of the batch production record is performed, as required by 21 C.F.R. § 111.255(c);

(7) Hold components, dietary supplements, packaging, and labels under conditions that do not lead to the mix-up, contamination, or deterioration of components, dietary supplements, packaging, and labels, as required by 21 C.F.R. § 111.455(c);

(8) Conduct all required material reviews and make all required disposition decisions, as required by 21 C.F.R. § 111.113(a); and

(9) Use equipment and utensils that are of appropriate design, construction, and workmanship to enable them to be suitable for their intended use and to be adequately cleaned and properly maintained, as required by 21 C.F.R. § 111.27(a);

E. Defendants recall and destroy, under FDA's supervision, all unexpired drugs and dietary supplements manufactured, processed, packed, labeled, held, and/or distributed

during the time period beginning August 1, 2010 through and including the date of entry of this Decree. Defendants shall bear the costs of destruction and the costs of FDA's supervision. Defendants shall not dispose of any such products in a manner contrary to the provisions of the Act, any other federal law, or the laws or any State or Territory, as defined in the Act, in which the products are disposed;

F. Should the Labeling Expert or Dietary Supplement CGMP Expert (collectively, "Experts") identify any deficiencies in their reports as described in paragraphs 8(B) and 8(D):

(1) Defendants shall report to FDA and the Experts in writing the actions they have taken to correct such deficiencies; and

(2) The Experts shall certify in writing to FDA whether, based upon the Experts' further review and/or inspections(s), Defendants' facility and their methods, processes, and controls used to manufacture, process, prepare, pack, label, hold, or distribute their dietary supplements (and all products labeled as such) and drugs appear to be in compliance with the Act, its implementing regulations, and this Decree; and whether Defendants have removed all claims from each of their product labels, labeling, websites owned or controlled by Defendants, and in any other media that cause any of Defendants' products to be drugs within the meaning of the Act;

G. Defendants certify in writing to FDA that none of their products intended for human use, including, but not limited to, bodybuilding, sexual enhancement, and/or weight-loss products, contain Active Pharmaceutical Ingredients, steroids, or steroid analogs;

H. FDA representatives inspect Defendants' facility to determine whether the requirements of this Decree have been met and whether Defendants are operating in conformity with this Decree, the Act, and its implementing regulations; and

I. Defendants have reimbursed FDA for the costs of all FDA inspections, investigations, supervision, analyses, examinations, and reviews that FDA deems necessary to evaluate Defendants' compliance with paragraph 8, at the rates set forth in paragraph 15 below;

J. FDA notifies Defendants in writing that they appear to be in compliance with the requirements set forth in paragraphs 8(A)-(G) and (I) of this Decree. In no circumstance shall FDA's silence be construed as a substitute for written notification.

Nothing in this paragraph shall prevent the individual Defendants from seeking and/or obtaining employment at retail stores that sell dietary supplements, provided the individual Defendants have no ownership interest in such retail stores or the dietary supplements sold therein.

9. Within ten (10) business days after the entry of this Decree, Defendants, under FDA's supervision, shall destroy all dietary supplements, all products labeled as such, and all drugs, including components of such articles, that are in Defendants' possession, custody, or control as of the date of entry of this Decree. Defendants shall bear the costs of destruction and the costs of FDA's supervision. Defendants shall not dispose of any such products in a manner contrary to the provisions of the Act, any other federal law, or the laws or any State or Territory, as defined in the Act, in which the products are disposed.

10. Upon resuming operations after complying with the requirements of paragraph 8 and receiving FDA's written notification pursuant to paragraph 8(J), Defendants shall retain an independent person or persons who shall meet the criteria described in paragraph 8(B) to conduct

audit inspections of Defendants' facility no less frequently than once every six (6) months for a period of no less than five (5) years (hereinafter, the "Auditor"). The first audit shall occur not more than six months after Defendants have received FDA's written notification pursuant to paragraph 8(J). If Defendants choose, the Auditor may be the same person or persons retained as the Labeling Expert or Dietary Supplement CGMP Expert described in paragraphs 8(B)-(C).

A. At the conclusion of each audit inspection, the Auditor shall prepare a detailed written audit report ("Audit Report") analyzing whether Defendants are in compliance with this Decree, the Act, and its implementing regulations, and identifying any deviations from such requirements ("Audit Report Observations").

B. Each Audit Report shall contain a written certification that the Auditor:

(a) has personally reviewed all of Defendants' product labels, labeling, and websites; and

(b) personally certifies whether the product labels, labeling, and internet websites do not make claims that cause Defendants' products to be drugs within the meaning of the Act.

C. As a part of every Audit Report, the Auditor shall assess the adequacy of corrective actions taken by Defendants to correct all previous Audit Report Observations. The Audit Reports shall be delivered contemporaneously to Defendants and FDA by courier service or overnight delivery service, no later than ten (10) business days after the date the Audit Inspection is completed. In addition, Defendants shall maintain the Audit Reports in separate files at Defendants' facility and shall promptly make the Audit Reports available to FDA upon request.

D. If an Audit Report contains any observations indicating that Defendants' dietary supplements, products labeled as such, and/or drugs are not in compliance with this Decree, the Act, or its implementing regulations, Defendants shall, within fifteen (15) business

days of receipt of the Audit Report, correct those observations, unless FDA notifies Defendants that a shorter time period is necessary. If, after receiving the Audit Report, Defendants believe that correction of the deviations will take longer than fifteen (15) business days, Defendants shall, within ten (10) business days of receipt of the Audit Report, submit to FDA in writing a proposed schedule for completing corrections ("Audit Correction Schedule"). The Audit Correction Schedule must be reviewed and approved by FDA in writing prior to implementation by Defendants. In no circumstance shall FDA's silence be construed as a substitute for written approval. Defendants shall complete all corrections according to the approved Audit Correction Schedule. Immediately upon correction, Defendants shall submit documentation of their corrections to the Auditor. Within twenty (20) business days of the Auditor's receipt of Defendants' documentation of corrections, unless FDA notifies Defendants that a shorter time period is necessary, or within the time period provided in a correction schedule approved by FDA, the Auditor shall review the actions taken by Defendants to correct the Audit Report Observations. Within five (5) business days of beginning that review, the Auditor shall report in writing to FDA whether each of the Audit Report Observations has been corrected and, if not, which Audit Report Observations remain uncorrected.

11. Upon entry of this Decree, Defendants, and all of their directors, officers, agents, representatives, employees, attorneys, successors and assigns, and any and all persons or entities in active concert or participation with any of them, are permanently restrained and enjoined under 21 U.S.C. § 332(a) from directly or indirectly doing or causing to be done any of the following acts:

A. Violating 21 U.S.C. § 331(a), by introducing or delivering, or causing to be introduced or delivered, into interstate commerce drugs that are misbranded within the meaning of 21 U.S.C. § 352(f)(1);

B. Violating 21 U.S.C. § 331(k), by causing drugs that Defendants hold for sale after shipment in interstate commerce to become misbranded within the meaning of 21 U.S.C. § 352(f)(1);

C. Violating 21 U.S.C. § 331(a), by introducing or delivering, or causing to be introduced or delivered, into interstate commerce food (dietary supplements) that is adulterated within the meaning of 21 U.S.C. § 342(g)(1); and

D. Violating 21 U.S.C. § 331(k), by causing food (dietary supplements) that Defendants hold for sale after shipment in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 342(g)(1).

12. If, at any time after this Decree has been entered, FDA determines, based on the results of an inspection, a review of Defendants' products, product labels, labeling, or websites owned or controlled by Defendants, a report prepared by Defendants' Experts or the Auditor, or any other information, that Defendants have failed to comply with any provision of this Decree, have violated the Act or its implementing regulations, or that additional corrective actions are necessary to achieve compliance with the Act, applicable regulations, and/or this Decree, FDA may, as and when it deems necessary, notify Defendants in writing of the noncompliance and order Defendants to take appropriate corrective action, including, but not limited to, ordering Defendants to immediately take one or more of the following actions:

A. Cease manufacturing, processing, packing, labeling, holding, and/or distributing any or all dietary supplements, all products labeled as such, and/or all drugs;

B. Recall, at Defendants' expense, any dietary supplement, any product labeled as such, and/or any drug that in FDA's judgment is adulterated, misbranded, or otherwise in violation of this Decree, the Act, or its implementing regulations;

C. Revise, modify, expand, or continue to submit any reports or plans prepared pursuant to this Decree;

D. Submit additional reports or information to FDA as requested;

E. Issue a safety alert; and/or

F. Take any other corrective actions as FDA, in its discretion, deems necessary to bring Defendants into compliance with this Decree, the Act, or its implementing regulations.

This remedy shall be separate and apart from, and in addition to, any other remedy available to the United States under this Decree or under the law.

13. Upon receipt of any order issued by FDA pursuant to paragraph 12, Defendants shall immediately and fully comply with the terms of the order. Any cessation of operations or other action described in paragraph 12 shall continue until Defendants receive written notification from FDA that Defendants appear to be in compliance with this Decree, the Act, and its implementing regulations, and that Defendants may resume operations. The cost of FDA inspections, sampling, testing, travel time, and subsistence expenses to implement the remedies set forth in paragraph 12 shall be borne by Defendants at the rates specified in paragraph 15.

14. Representatives of FDA shall be permitted, without prior notice and as and when FDA deems necessary, to inspect Defendants' places of business, and without prior notice, take any other measures necessary to monitor and ensure continuing compliance with the terms of this Decree. During inspections, FDA representatives shall be permitted to: have immediate access

to buildings, equipment, raw ingredients, in-process materials, finished products, containers, packaging material, labeling, and other material therein; take photographs and make video recordings; take samples of Defendants' raw ingredients, in-process materials, finished products, containers, packaging material, labeling, and other material; and examine and copy all records relating to the manufacture, processing, packing, labeling, holding, and distribution of any and all dietary supplements and their components. The inspections shall be permitted upon presentation of a copy of this Decree and appropriate credentials. The inspection authority granted by this Decree is separate from, and in addition to, the authority to make inspections under the Act, 21 U.S.C. § 374.

15. Defendants shall reimburse FDA for the costs of all FDA inspections, investigations, supervision, analyses, examinations, and reviews that FDA deems necessary to evaluate Defendants' compliance with any part of this Decree at the standard rates prevailing at the time the costs are incurred. As of the date of entry of this Decree, these rates are: $87.57 per hour or fraction thereof per representative for inspection and investigative work; $104.96 per hour or fraction thereof per representative for analytical or review work; $0.565 per mile for travel expenses by automobile; government rate or the equivalent for travel by air or other means; and the published government per diem rate for subsistence expenses where necessary. In the event that the standard rates applicable to FDA supervision of court-ordered compliance are modified, these rates shall be increased or decreased without further order of the Court.

16. Within ten (10) business days after the date of Defendants' notice to FDA as described in paragraph 7, Defendants shall post a copy of this Decree in a common area at Defendants' facility and at any other location at which Defendants conduct business and shall ensure that the Decree remains posted for as long as the Decree remains in effect.

17. Within ten (10) business days after the entry of this Decree, Defendants shall provide a copy of the Decree by personal service or certified mail (return receipt requested) to each and all of their directors, officers, agents, representatives, employees, attorneys, successors and assigns, and any and all persons or entities in active concert or participation with any of them ("Associated Persons"). Within twenty (20) business days after the date of entry of this Decree, Defendants shall provide to FDA an affidavit stating the fact and manner of their compliance with this paragraph, identifying the names, addresses, and positions of all persons who have received a copy of this Decree.

18. In the event that any of the Defendants becomes associated with any additional Associated Person(s) at any time after entry of this Decree, Defendants shall within ten (10) business days after the commencement of such association: (a) provide a copy of this Decree, by personal service or certified mail (restricted delivery, return receipt requested), to such Associated Person(s); and (b) provide to FDA an affidavit stating the fact and manner of compliance with this paragraph, identifying the names, addresses, and positions of all Associated Persons who received a copy of this Decree pursuant to this paragraph.

19. Defendants shall notify FDA in writing at least fifteen (15) business days before any change in ownership, name, or character of their business that occurs after entry of this Decree, including an incorporation, reorganization, creation of a subsidiary, relocation, dissolution, bankruptcy, assignment, sale, or any other change in the structure or identity of Mira Health Products Ltd., or the sale or assignment of any business assets, such as buildings, equipment, or inventory that may affect obligations arising out of this Decree. Defendants shall provide a copy of this Decree to any prospective successor or assign at least twenty (20) business days prior to any sale or assignment. Defendants shall furnish FDA with an affidavit of

compliance with this paragraph no later than ten (10) business days prior to such assignment or change in ownership.

20. All notifications, correspondence, and communications to FDA required by the terms of this Decree shall be addressed to the District Director, New York District Office, 158-15 Liberty Avenue, Jamaica, New York, 11433.

21. Should Defendants fail to comply with any provision of this Decree, the Act, or its implementing regulations, including any time frame imposed by this Decree, then Defendants shall pay to the United States of America: five thousand dollars ($5,000) in liquidated damages for each day such violation continues; an additional sum of one thousand five hundred dollars ($1,500) in liquidated damages per day, per violation for each violation of this Decree, the Act, and/or its implementing regulations; and an additional sum in liquidated damages equal to twice the retail value of any distributed dietary supplements that are adulterated or otherwise in violation of this Decree, the Act, or its implementing regulations. The remedy in this paragraph shall be in addition to any other remedies available to the United States under this Decree, any other Decree to which Defendants are subject, or the law.

22. Should the United States bring and prevail in a contempt action to enforce the terms of this Decree, Defendants shall, in addition to other remedies, reimburse the United States for its attorneys' fees (including overhead), investigational and analytical expenses, expert witness fees, and court costs relating to such contempt proceedings.

23. Defendants shall abide by the decisions of FDA, and FDA's decisions shall be final. All decisions conferred upon FDA in this Decree shall be vested in FDA's discretion and, if contested, shall be reviewed by this Court under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A). Review by the Court of any FDA decision rendered pursuant to this

Decree shall be based exclusively on the written record before FDA at the time the decision was made. No discovery shall be taken by either party.

24. No sooner than five (5) years after satisfying the obligations of paragraphs 8(A)-(G) and (I) and receiving written notification from FDA pursuant to paragraph 8(J) of this Decree, Defendants may petition this Court for an order to dissolve this Decree. If Defendants have maintained, to FDA's satisfaction, a state of continuous compliance with this Decree, the Act, and all applicable regulations during the five (5) years preceding Defendants' petition, the United States will not oppose such petition.

25. This Court retains jurisdiction over this action and the parties thereto for the purpose of enforcing and modifying this Decree and for the purpose of granting such additional relief as may be necessary or appropriate.

SO ORDERED, this ___ day of _____, 2014.

_____
UNITED STATES DISTRICT JUDGE

Entry consented to:

For Defendants

MICHAEL S. RAGNO
Individually and on behalf of
Mira Health Products Ltd., as its Owner
and Chief Executive Officer

MICHAEL S. RAGNO, JR.
Individually and on behalf of
Mira Health Products Ltd., as its
Quality Assurance/Quality Control
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Entry consented to:

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Individually and on behalf of
Mira Health Products Ltd., as its Owner
and Chief Executive Officer

MICHAEL S. RAGNO, JR.
Individually and on behalf of
Mira Health Products Ltd., as its
Quality Assurance/Quality Control
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